

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

**GALDERMA LABORATORIES, L.P., GALDERMA
S.A., GALDERMA SKIN HEALTH S.A.,**
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Cross-Appellant

2019-2396, 2020-1213

Appeals from the United States District Court for the District of Delaware in No. 1:17-cv-01783-RGA, Judge Richard G. Andrews.

Decided: January 29, 2020

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JOHN C. O'QUINN, Kirkland & Ellis LLP, Washington, DC, for defendant-cross-appellant. Also represented by WILLIAM H. BURGESS; LEORA BEN-AMI, New York, NY.

Before MOORE, O’MALLEY, AND STOLL, *Circuit Judges*.
O’MALLEY, *Circuit Judge*.

This patent infringement suit arises from the filing of Teva Pharmaceuticals USA, Inc.’s (“Teva’s”) Abbreviated New Drug Application (“ANDA”) No. 210019. In its ANDA, Teva seeks approval to market a generic version of Soolantra®, a pharmaceutical product marketed by Plaintiffs Galderma Laboratories, L.P., Galderma S.A., and Nestlé Skin Health S.A. (collectively, “Galderma”). Following a bench trial, the U.S. District Court for the District of Delaware entered final judgment for Teva, holding that the asserted claims of U.S. Patent Nos. 9,089,587 (“the ‘587 patent”); 9,233,117 (“the ‘117 patent”); and 9,233,118 (“the ‘118 patent”) were invalid for anticipation under 35 U.S.C. § 102. Galderma appeals from the district court’s judgment. Following entry of judgment, Galderma sought and obtained from the district court an injunction pending appeal pursuant to Federal Rule of Civil Procedure 62(d). Teva cross-appeals from the district court’s injunction order. For the reasons discussed below, we *reverse* and *remand* the district court’s judgment and *dismiss* as moot Teva’s cross-appeal.¹

¹ Given the parties’ detailed briefing of these issues in connection with Teva’s motion to stay the injunction order (addressed below), the straightforward nature of the issues presented, and the need to resolve this dispute and return it to the district court expeditiously, we see no value in scheduling oral argument in this case. Accordingly, we proceed to rule on this appeal on the papers.

I. BACKGROUND

A. The Claimed Technology

Galderma is the holder of approved New Drug Application (“NDA”) No. 206255 for Soolantra®, a topical pharmaceutical formulation containing 1% ivermectin. Soolantra® is indicated for the treatment of inflammatory lesions of rosacea, a skin disorder characterized by facial flushing and redness. The patents-in-suit are listed in the Orange Book for Soolantra® and are directed to methods of treating papulopustular rosacea (“PPR”), using topical ivermectin compositions. PPR, a subtype of rosacea, is a chronic inflammatory disorder that results in facial papules and pustules and is characterized by the presence of inflammatory lesions. Soolantra®, approved by the FDA in 2014, is the first ever ivermectin-based treatment for rosacea.

Galderma asserted the following claims at trial: claim 12 of the ’587 patent; claims 2, 3, and 6 of the ’117 patent; and claims 6, 7, 10, and 11 of the ’118 patent. The asserted claims recite methods of treating inflammatory lesions of rosacea through topical administration of 1% ivermectin once daily to patients with inflammatory lesions of rosacea. The claims also recite certain efficacy benchmarks resulting from the treatment methods. These bench marks measure certain parameters, including: (1) lesion count reduction, *i.e.*, the difference in the number of inflammatory lesions before and after treatment; (2) Investigator’s Global Assessment (“IGA”) success rate, *i.e.*, the percentage of patients who achieve an IGA of 0 to 1 on a five-point scale of rosacea severity;² and, (3) relapse-free time, *i.e.*, the time period between a patient’s IGA success rate of 0 or 1 to the

² The five-point scale characterizes rosacea severity as follows: 0 (clear), 1 (almost clear), 2 (mild), 3 (moderate), and 4 (severe). ’587 patent, Table 1.

patient's first reoccurrence of an IGA of 2 or more. See '587 patent, 6:63–7:25. The claimed efficacy benchmarks are:

- (1) 'a significant reduction in inflammatory lesion count in the subject' ('587 patent, claim 12; '118 patent, claims 6, 7, 10, 11);
- (2) 'a significant improvement in at least one selected from the group consisting of a higher investigator's global assessment success rate and a delayed time to first relapse in the subject in comparison to that achieved by topically administering to the subject, twice daily, a second pharmaceutical composition comprising 0.75% by weight metronidazole' ('587 patent, claim 12);
- (3) 'as early as 2 weeks after the initial administration of the pharmaceutical composition, a significant reduction in inflammatory lesion count' ('117 patent, claims 2, 3, 6; '118 patent, claims 7, 10, 11);
- (4) 'as early as 2 weeks after the initial administration of the pharmaceutical composition, a significant reduction in inflammatory lesion count,' 'wherein the subject has moderate to severe papulopustular rosacea before the treatment,' and 'wherein the subject has 15 or more of the inflammatory lesions before the treatment' ('117 patent, claim 6);
- (5) 'more reduction in inflammatory lesion count in the subject in comparison to that achieved by topically administering to the subject, twice daily, a second pharmaceutical composition comprising 0.75% by weight metronidazole' ('117 patent, claim 2; '118 patent, claim 10); and
- (6) 'longer relapse-free time of the inflammatory lesions of rosacea in the subject in comparison to that achieved by twice daily topically administering to

the subject a second pharmaceutical composition comprising 0.75% by weight metronidazole' ('117 patent, claim 3; '118 patent, claim 11).

Galderma Labs. L.P. v. Teva Pharm. USA, Inc., 390 F. Supp. 3d 582, 590 (D. Del. 2019).

The parties agreed that the terms “significant reduction” or “significant improvement” meant “a reduction/improvement that is statistically significant, not due to chance alone, which has a p-value of 0.05 or less.” J.A. 4374. And they agreed that “time to first relapse” or “relapse-free time” meant “the time elapsed between initial successful treatment to an IGA of rosacea of 0 or 1 to the first reoccurrence of the IGA to 2 or more in a subject.” *Id.*

It is undisputed that the Soolantra® formulation necessarily achieves the claimed efficacy limitations.

B. Procedural History

On December 30, 2016, Teva filed its ANDA directed to a generic 1% ivermectin cream. In response to Teva’s paragraph IV certification asserting that the claims of the patents-in-suit were invalid, unenforceable, and/or not infringed, Galderma filed this suit against Teva, alleging infringement pursuant to 35 U.S.C. § 271(d)(2)(A). Teva stipulated to infringement of claim 6 of the '118 patent. The district court held a bench trial in June 2019. Teva asserted that the claims at issue were invalid as anticipated by U.S. Patent No. 5,952,372 (“McDaniel”) or U.S. Patent No. 7,550,440 (“Manetta”). Teva also argued that the asserted claims were invalid for obviousness over Manetta alone, or Manetta in combination with McDaniel and certain other prior art references. J.A. 6053–62. Teva further argued that the asserted claims lack written description support. J.A. at 6042–43.

Following post-trial briefing, the district court issued an opinion finding each of the asserted claims invalid for anticipation by McDaniel. *Galderma Labs.*, 390 F. Supp.

3d at 584. The district court found that McDaniel expressly discloses: methods for treatment of rosacea, including inflammatory lesions of PPR; a topical formulation containing about 1–5% ivermectin; and, once-daily application of ivermectin. *Id.* at 586–89. It also found that McDaniel inherently disclosed the claimed efficacy limitations. *Id.* at 589–92. This finding of inherency was based on the parties’ stipulation that “Manetta enables McDaniel in 2012 as to the formulation.” *Id.* at 591. The district court concluded that McDaniel discloses “the same ivermectin formulation as in the asserted claims.” *Id.* at 591–92. According to the district court, “as of 2012, before the critical dates of the asserted claims, a person of ordinary skill in the art would have been able to practice McDaniel’s disclosed treatment method with Manetta’s formulation without undue experimentation.” *Id.* at 591. It is undisputed that Manetta discloses the Soolantra formulation. J.A. 6015, ¶¶ 93–94; J.A. 15010–11.

The district court did not address Teva’s anticipation challenge based on Manetta. And, because it found all asserted claims invalid for anticipation, the court did not reach Teva’s arguments concerning obviousness and lack of written description. The district court entered judgment on August 29, 2019.

On September 6, 2019, Galderma timely filed a notice of appeal. Shortly thereafter, Teva launched its generic drug product. In response, Galderma filed an emergency motion for a stay pending appeal pursuant to Federal Rule of Civil Procedure 62(d). At the hearing for this motion, the district court noted that Galderma had raised a substantial issue with the finding of anticipation, leaving the court without confidence that this decision would be affirmed. J.A. 15862–63. The court granted Galderma’s motion, enjoining Teva from marketing its generic product.

Teva then filed a motion with this court pursuant to Federal Rule of Appellate Procedure Rule 8, asking us to

stay or dissolve the injunction. Because Teva did not first file a notice of appeal from the injunction order, we asked the parties to address whether we had authority to grant Teva's requested relief. In response, Teva timely filed a notice of cross-appeal. We granted Teva's Rule 8 motion on December 12, 2019 and stayed the district court's injunction. *See Order, Galderma Labs. L.P. v. Teva Pharm. USA, Inc.*, No. 19-2053 (Fed. Cir. Dec. 12, 2019), ECF No. 43.

On appeal, Galderma challenges the district court's finding of anticipation of the asserted claims. As to the cross-appeal, Teva does not intend to further brief the injunction issue, noting that its requested relief has already been granted. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

On appeal from a bench trial, we review a district court's conclusions of law de novo and its findings of fact for clear error. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1337 (Fed. Cir. 2005). "Anticipation is a question of fact, and a district court's findings on this issue are reviewed for clear error." *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1358 (Fed. Cir. 2014). A factual finding is clearly erroneous if, upon review of the evidence, a reviewing court is "left with the definite and firm conviction that a mistake has been made." *Spectrum Pharm., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1333 (Fed. Cir. 2015). "[I]f the trial court bases its findings upon a mistaken impression of applicable legal principles, the reviewing court is not bound by the clearly erroneous standard." *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 855 (1982).

B. Anticipation

On appeal, Galderma challenges the district court's (1) use of multiple references for its anticipation analysis; and (2) finding of inherency based on "a mere possibility."

The parties also dispute whether McDaniel expressly discloses the claimed efficacy limitations. As explained below, we agree with Galderma that the district court erred in its inherent anticipation analysis. Moreover, we read the district court’s opinion to implicitly find that McDaniel lacks an express disclosure of the claimed efficacy limitations. We do not consider this finding to be clearly erroneous.

1. Reliance on Multiple References

A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention, either expressly or inherently. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). An anticipatory prior art reference must also “enable one with ordinary skill in the art to practice the invention.” *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1342 (Fed. Cir. 2005) (internal quotations and citations omitted). “As long as the reference discloses all of the claim limitations *and* enables the ‘subject matter that falls within the scope of the claims at issue,’ the reference anticipates.” *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (emphasis added) (quoting *Schering Corp.*, 339 F.3d at 1380–81).

Galderma argues that the district court erred by finding the asserted claims anticipated based on disclosures found in two references, in contravention of settled law that anticipation must be based on disclosure in a single reference. According to Galderma, although the district court was permitted to look to other references to interpret the allegedly anticipatory reference, it was strictly prohibited from using additional references “for a very specific teaching.” Galderma’s Br. 22 (citing *Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 726 F.2d 724, 727 (Fed. Cir. 1984)). Galderma argues that the district court erred by relying on Manetta for its teaching of the Soolantra formulation. *Id.* at 23. In Galderma’s view, based on the parties’ stipulation that McDaniel’s formulation was enabled

by Manetta, the district court incorporated one of the Manetta formulations into McDaniel, erroneously finding the asserted claims anticipated.

Galderma further contends that the district court confused enablement with anticipatory disclosure. *Id.* at 23–26. Galderma argues that we have looked to additional references “solely to show *enablement* of an anticipatory reference,” not, as here, for “whether an enabled reference *discloses* all claim limitations.” *Id.* at 25 (citing *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1372 (Fed. Cir. 2001)). According to Galderma, Manetta’s enablement of McDaniel’s formulation only means that a person of ordinary skill in the art (“POSA”) could practice the general formulations disclosed in McDaniel. It cannot mean that McDaniel discloses the specific formulation disclosed in Manetta.

Teva, on the other hand, sees no error in the district court’s finding of anticipation. It argues that anticipation is evaluated from the perspective of a POSA and the knowledge of a POSA can be shown with extrinsic evidence, “without running afoul of the single-reference rule for anticipation.” Teva’s Br. 33. According to Teva, Galderma’s stipulation that “Manetta enables McDaniel in 2012 as to the formulation,” is “directly relevant evidence” of the perspective of a POSA. *Id.* at 34. Teva argues that there is no error because “[i]t follows [from the parties’ stipulation] that a skilled artisan with McDaniel in hand would envisage” the specific formulation disclosed in Manetta. *Id.* at 35.

Teva further argues that the district court’s findings are consistent with our precedent. It argues that disclosure of a genus (here, McDaniel’s disclosure of a 1–5% ivermectin formulation) can anticipate a claimed species if a POSA would discern or possess the species (here, the Soolantra formulation) upon reading the disclosure. *Id.* (citing *Bristol-Myers*, 246 F.3d at 1380). According to Teva,

Manetta’s Soolantra is “undoubtedly a species within the scope of McDaniel’s disclosure,” and, given that this formulation necessarily achieves the claimed results, a POSA’s possession of the formulation before the critical date anticipates. *Id.* (citing *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005)).

Teva’s arguments ignore the axiom that a patent claim can only be invalid for anticipation if a single reference discloses each and every limitation of the claimed invention. Turning to another reference “for a very specific teaching” runs afoul of these settled principles. *See, e.g., Dart Indus.*, 726 F.2d at 727 (rejecting an anticipation challenge where the challenger relied on two additional articles “for a very specific teaching, not for any light they shed on what [the anticipatory reference] would have meant to those skilled in the art”). Here, the district court erred by finding the asserted claims anticipated by the disclosures of McDaniel and Manetta, in contravention of settled law.

We reject Teva’s arguments that the doctrine of enablement justified the district court’s reliance on Manetta for a specific teaching. In so arguing, Teva confuses the concepts of anticipation and enablement, just as the district court did. Whether a prior art reference is enabled is a separate question from whether it discloses, expressly or inherently, the claimed limitations at issue. Here, the parties’ stipulation meant only one thing: in 2012, a POSA would have been able to practice the general formulations disclosed in McDaniel, *i.e.*, 1–5% ivermectin, “formulated into a cosmetically-acceptable topical lotion, cream, or gel.” McDaniel at 2:66–3:10. The stipulation cannot mean, as Teva suggests, that McDaniel discloses the specific Soolantra formulation.

Our decision in *Bristol-Myers* is instructive. In *Bristol-Myers*, we held that certain method of treatment claims directed to “premedicating” were anticipated by the prior art reference “Kris” suggesting premedicating generally, even

though Kris did not “actually employ premedication.” 246 F.3d at 1378. We clarified that it was permissible to “look to any references that establish that Kris’s suggestion of [premedicating] would have been enabling to one of skill in the art more than one year prior to [the] earliest filing date of [the patent].” *Id.* at 1379. At the same time, we found that certain other claims, directed to specific classes of pre-medicaments (“steroids, antihistamines, H₂-receptor antagonists, and combinations thereof”), were not anticipated by Kris, which disclosed “only the use of premedicaments generally.” *Id.* at 1372, 1380. For this second set of claims, we refused to turn to other prior art references disclosing the use of steroids and H₂-histamine antagonists as pre-medicaments, because Kris did not contain this specific disclosure. *Id.* at 1380.

The difference between our finding of anticipation of the first set of claims in *Bristol-Myers* and the district court’s finding of anticipation in the present case, is that in *Bristol-Myers*, the asserted anticipatory reference contained the very disclosure that was found to be enabling based on other references (premedicating generally). By contrast, here, McDaniel does not contain the specific disclosure that is necessary for a finding of anticipation: an ivermectin formulation (such as Soolantra®) that necessarily achieves the claimed efficacy limitations. We refuse to look to Manetta to incorporate a specific disclosure not found in McDaniel, just as we refused in *Bristol-Myers* to look beyond Kris for a disclosure of the specific premedicaments claimed in the second set of claims at issue in that case.

In suggesting that “[i]t follows [from the parties’ stipulation] that a skilled artisan with McDaniel in hand would envisage” the Soolantra® formulation, Teva’s Br. 35, Teva makes the impermissible leap from enablement to disclosure. The parties’ stipulation concerned the enablement of McDaniel. What a POSA “envisages,” on the other hand, is undoubtedly a question of disclosure, not enablement.

What a POSA “envisages” from reading a reference is relevant to whether a reference discloses the claim elements “arranged as in the claim.” *Net MoneyIn, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). Though Manetta enables an embodiment of McDaniel, it does not necessarily follow that a POSA reading McDaniel would at once envisage the undisclosed specific Soolantra® formulation that satisfies the claimed efficacy limitations. In any event, we have previously rejected the proposition that “a reference missing a limitation can anticipate a claim if a skilled artisan viewing the reference would ‘at once envisage’ the missing limitation.” See *Nidec Motor Corp. v. Zhongshan Bd. Queen Motor Co. Ltd.*, 851 F.3d 1270, 1274–75 (Fed. Cir. 2017). Here, the district court was not permitted “to fill in missing limitations simply because a skilled artisan would immediately envision them.” *Id.*

We also reject Teva’s arguments that possession of the Soolantra® formulation by a POSA before the critical date anticipates because Soolantra® is “undoubtedly a species within the scope of McDaniel’s disclosure.” Teva’s Br. 35. Teva has not established that McDaniel’s disclosure of 1–5% topical ivermectin is a small enough genus that the species is anticipated. To the contrary, Teva’s own expert testified that a 1% ivermectin formulation can be achieved in “thousands and thousands of possible” ways. J.A. 6486–87.

Accordingly, we conclude that the district court erred in looking outside McDaniel in its anticipation analysis.

2. Inherency Based on Mere Possibility

“[A] limitation or the entire invention is inherent and in the public domain if it is the ‘natural result flowing from’ the explicit disclosure of the prior art.” *Schering Corp.*, 339 F.3d 1373 at 1379 (citations omitted). Inherency “may not be established by probabilities or possibilities.” *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011).

On appeal, Galderma argues that the district court erroneously found that McDaniel inherently discloses the claimed efficacy limitations. Galderma's Br. 28–32. According to Galderma, the district court erroneously based this conclusion on the mere possibility that a POSA would have been able to practice McDaniel's disclosed method with Soolantra®. Teva, on the other hand, argues that McDaniel “discloses” the Soolantra® formulation, and therefore it inherently anticipates the claimed efficacy limitations, regardless of any other formulations McDaniel also discloses. Teva's Br. 38–39.

We agree with Galderma that the district court's finding of inherent anticipation is erroneous. As we have explained, the district court's conclusion that McDaniel discloses the Soolantra® formulation conflates the principles of enablement and anticipation. The proper inquiry for inherent anticipation is whether the claimed efficacy limitations “necessarily result” from practicing McDaniel. *See, e.g., Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 960–61 (Fed. Cir. 2014) (affirming judgment that claims were not inherently anticipated where the prior art only showed that the limitation might occur, not that it inevitably occurred). What a POSA would have been able to practice based on Manetta's disclosure is not at issue.

The district court mistakenly relied on *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005) to find inherent anticipation. In *Perricone*, the anticipatory reference “disclosed compositions includ[ing] all the various ingredients in the concentrations claimed by [the patentee].” 432 F.3d at 1376. We found that “the district court correctly applied the inherency doctrine” because the prior art reference at issue “disclose[d] the very same composition” as the claimed invention and taught its use in the manner claimed. *Id.* at 1379. We concluded that “[u]sing the same composition claimed by [the patentee] in the same manner claimed by [the patentee] naturally results in the same claimed . . . benefits.” *Id.*

Unlike *Perricone*, here, McDaniel does not disclose the “very same composition” as the patents-in-suit; it only discloses topical ivermectin formulations generally. The record does not show that practicing McDaniel’s general disclosure of 1% ivermectin, “formulated into a cosmetically-acceptable topical lotion, cream, or gel,” necessarily achieves the claimed efficacy limitations. Teva did not demonstrate that the use of any such formulation inevitably results in the claimed efficacies. Notably, Teva’s own formulation expert testified that formulation parameters such as excipients can impact drug release, J.A. 6491, which affects whether a formulation has “any sort of therapeutic value.” J.A. 6481.

This is not a case, as Teva suggests, of an anticipating reference disclosing non-anticipating alternatives. Teva’s Br. 39–40. It is true that anticipation is not defeated by a showing that the allegedly anticipating reference also discloses non-anticipating alternatives. *See, e.g., Perricone*, 432 F.3d at 1376. But that is not the question before us. The inquiry here is whether the claimed efficacy limitations are an inherent result of practicing McDaniel’s disclosed methods. The answer is no because: (1) McDaniel does not disclose the specific Soolantra® formulation; and (2) as Teva’s expert acknowledged, variation in formulation parameters will undoubtedly affect the results achieved from the use of McDaniel’s disclosed formulations. Teva has provided no basis for us to conclude with certainty that all 1% formulations within the scope of McDaniel’s disclosure will inevitably achieve the claimed efficacy limitations.

Accordingly, we conclude that the district court’s inherent anticipation analysis was clearly erroneous.

3. McDaniel’s Express Disclosures

Finally, we address whether McDaniel expressly discloses the efficacy limitations. Galderma argues that the district court correctly found that McDaniel does not

expressly disclose the claimed efficacy limitations. Galderma's Reply Br. 14–15. Teva, on the other hand, insists that the district court made no such finding. Teva's Br. 41–42. Instead, Teva argues that McDaniel expressly discloses all the efficacy limitations. *Id.* at 43–55.

As to whether the district court found that McDaniel lacks an express disclosure of the claimed efficacy limitations, we conclude that such a finding is implicit in the court's analysis. The district court's "Findings of Fact" Nos. 9–11 are reproduced below:

9. McDaniel explicitly discloses a treatment method comprising (1) topically administering, (2) once daily, (3) to a skin area affected by the inflammatory lesions of papulopustular rosacea, (4) a pharmaceutical composition comprising about 1% by weight ivermectin and a pharmaceutically acceptable carrier.

10. McDaniel inherently discloses the treatment results of its treatment method as enabled by the Manetta formulation.

11. McDaniel anticipates claim 12 of the '587 patent, claims 2, 3, and 6 of the '117 patent, and claims 6, 7, 10, and 11 of the '118 patent.

Galderma Labs., 390 F. Supp. 3d at 585. In its analysis, the district court first explained how McDaniel expressly discloses every element of "the claimed treatment method," at the same time noting that it will "separately" address the "various efficacy limitations." *Id.* at 586–87. When addressing the claimed efficacy limitations, the district court stated that "the only remaining limitations are those relating to efficacy. Therefore, McDaniel anticipates the asserted claims if the efficacy limitations are inherent to the treatment method." *Id.* at 589–90 (emphases added). This language makes clear that the district court concluded that

McDaniel does not expressly disclose the efficacy limitations.

We see no clear error in this finding. Based on our review of the record, including the expert testimony addressing McDaniel's disclosures, we conclude that the district court did not clearly err in finding that McDaniel lacks an express disclosure of the claimed efficacy limitations. *See, e.g.*, J.A. 6819–23 (testimony of Dr. Thisted); J.A. 6841–46 (testimony of Dr. Webster); J.A. 6693–99, 6759–64 (testimony of Dr. Gallo).

Because the district court did not clearly err in finding that McDaniel lacks an express disclosure of the claimed efficacy limitations, and because the district court clearly erred in its inherent anticipation analysis, McDaniel does not anticipate. Accordingly, we reverse the district court's finding of anticipation.

C. Teva's Obviousness Arguments

The district court did not reach Teva's obviousness defense because it found the asserted claims anticipated by McDaniel. Teva invites us to affirm the judgment of invalidity by considering, in the first instance, the issue of obviousness of the asserted claims. As a court of review, that is not our role. We have declined in the past to reach invalidity issues not decided by the district court. *See, e.g.*, *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1585 (Fed. Cir. 1995). We see no reason to depart from that practice in this case.

D. Teva's Cross-Appeal

Because we have already granted the relief requested in Teva's cross-appeal, *see* No. 19-2396, ECF No. 43, we dismiss Teva's cross-appeal as moot.

III. CONCLUSION

For the foregoing reasons, we reverse and remand for the district court to consider Teva's remaining invalidity

GALDERMA LABS., L.P. v. TEVA PHARM. USA, INC.

17

defenses, and dismiss Teva's cross-appeal as moot. We have considered the parties' remaining arguments and find them unpersuasive.

**REVERSED AND REMANDED AS TO CASE NO.
2019-2396; DISMISSED AS TO CASE NO. 2020-1213**

COSTS

No costs.